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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

March 23, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Dan Zavidel
Chief Executive Officer
Gas House, Inc.
533 East Clark
Pocatello, Idaho 83205

PURGED

Ref. # - DEN-98-08

Dear Mr. Zavidel:

During an inspection of your firm, Gas House, Inc., 1177 South Swaner, Salt Lake City, Utah, on February 12 through 13, 1998, Investigators James E. Moore and Margaret M. Annes determined that your firm transfills liquid medical oxygen. Medical oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that your product, Oxygen, U.S.P., is adulterated in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection include, but are not limited to the following:

1. Failure to maintain complete records of any testing and standardization of laboratory reference standards [21 CFR 211.194(c)]. For example, the [illegible] Oxygen Analyzer is calibrated using nitrogen from a bulk stand tank which is not tested to the same precision and accuracy as a reference or calibration nitrogen gas from a speciality gas manufacturer or a supplier of standards, which gas is accompanied by a valid certificate of analysis.

2. Failure to calibrate laboratory instruments at suitable intervals in accordance with an established written program [21 CFR 211.160(b)(4)]. For example, the operation manual for the Oxygen Analyzer requires that the instrument be zeroed and the filter examined once a week. These checks are performed monthly.

3. Failure to have master production and control records that include complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed [21 CFR 211.186(b)(9)]. For example, the master production and control records in use referenced documents which were not in use such as data sheets, lacked some procedures such as for gauge calibration, and lacked reference to documentation being used such as filling records.

4. Failure to have a master production and control record prepared, dated, and signed by one person and independently checked, dated, and signed by a second person [21 CFR 211.186]. For example, the master production and control record in use was not signed and dated.

5. Failure to have batch production and control records which document each significant step in the manufacture of medicinal gas and include the identification of the person checking each significant step performed [21 CFR 211.188(b)]. For example, filling records did not allow documentation of the completion of each prefill inspection, rather, the record provided a list of prefill inspections and one block to be checked once all prefill inspections were complete.

6. Failure to follow written procedures for handling written and oral complaints [21 CFR 211.198]. For example, several oral complaints were received regarding cylinder valves in the past year; however, they were not recorded on the complaint form, EF-1.6, as required by the written complaint procedure.

7. Failure to train personnel engaged in the manufacture of medicinal gas in current good manufacturing practice regulations and written procedures [21 CFR 211.25(a)].

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As Chief Executive Officer, it is your responsibility to assure adherence with all requirements of the Good Manufacturing Regulations.

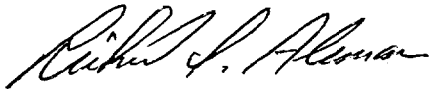
At the conclusion of the inspection, Investigators Moore and Annes issued a written report of observations (FDA 483) to you. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Federal Food, Drug, and Cosmetic Act; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

Please advise this office, in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Mr. Russell W. Gripp, Compliance Officer, at the above address.

Sincerely,



for Gary C. Dean
District Director

Enclosure:
As stated

PURGED

cc: Mr. Tom Little
President
Gas House, Inc.
4473 South 15 West
Idaho Falls, Idaho 83402

Ms. Mary Kay Smith
Regional Administrator
Health Care Finance Administration, DHHS Region VIII
Byron G. Rogers Federal Building
1961 Stout Street, Fifth Floor
Denver, Colorado 80294-3538